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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/538,761	06/10/2005	Takahiro Hori	P27982.A01	6796

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EXAMINER	
MELLON, DAVID C	
ART UNIT	PAPER NUMBER
1797	

NOTIFICATION DATE	DELIVERY MODE
01/14/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/538,761	HORI ET AL.	
	Examiner	Art Unit	
	DAVID C. MELLON	1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *6/10/2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *20051026*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Specification

1. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 1-3, 5- 9, 11, and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Novak (USP 2,341,114) in view of Motomura et al. (USP 5,667,684).

Regarding claim 1-3 and 5-7, Novak discloses a filter for blood and plasma transfusions in figure 1 comprising:

- a transparent cellulose casing (15 – cellulose casing would be "pouchy") with an inlet (opening 11 and inlet tube 13) and an outlet (outlet tube 19)
- a separation membrane securely held in the case (bag 10) which partitions the casing into two compartments (see in figure 1, inside of bag 10 and then outside of bag 10 but inside 15)
- the first compartment receives fluid to be treated and the second receives filtrate (since the inlet feeds into bag 10, inherently, the first compartment is a receiving compartment and then fluid filters through 10 to the second compartment of a filtrate compartment before exiting via outlet 19, see also C2/L23-33)
- The filter bag (10) is held in place securely (tight fitting bands – C2/L10-25 and C2/L47-50)
- The filter bag is tapered toward the forward end of the filter bag as viewed in a flow direction with the tapering beginning at the backward end or a

portion during the course of the flow to the forward end (See in figure 1 that filter bag 10 is tapered).

Novak does not disclose the use of a virus-removal membrane using a graft polymerization reaction to join a hydrophilic monomer to a porous membrane base to form a hydrophilic membrane with nanometer size pores for filtering viruses from the virus containing suspension.

Motomura et al. discloses a material for removing human immunodeficiency virus and related substances from blood, plasma, or other fluids (abstract) comprising a porous substrate on which a sulfuric group is immobilized (abstract). The material is a filter having an average pore diameter of 0.1 micrometers (100 nanometers) comprising a flat membrane (C5/L60-67). When the membrane is filtering plasma, it is preferable to use a diameter of 0.1 micrometers (C6/L60-67). The membrane is formed from a hydrophobic polymer and is surface modified by hydrophilic materials (C7/L25-38). The hydrophilic surface modification is preferably a side chain grafted to the substrate (C2/L18-27).

Novak and Motomura et al. are combinable because they are concerned with the same field of endeavor, namely that of plasma purification.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the filter for plasma treatment in a pouch of Novak to replace the filter of Novak with a filter such as the one disclosed by Motomura et al. for the purpose of removing HIV and related components to ensure higher purity and safety in blood and blood products used for transfusions.

Regarding claim 8, modified Novak discloses all of the claim limitations as set forth above. Novak further discloses that the bag is flexible (C2/L9-15 – "transparent casing 15 of cellulose", cellulose is a well-known flexible material).

Regarding claims 9 and 11, modified Novak discloses all of the claim limitations as set forth above. While Novak doesn't explicitly set forth that the second compartment has a volume sufficient to collect all of the filtrate obtained or that its volume is in the range of 100 to 800 cubic centimeters, it would have been obvious to one having ordinary skill in the art at the time the invention was made to optimize the size of the filtration bag such that its filtrate holding volume is capable of collecting the amount of filtrate taught and that the volume is between 100-800 cubic centimeters. It would have been obvious since in the medical field, blood and plasma container volumes for medical fluids are well known to generally fall within the 100-800 cubic centimeter range and specifically for blood products, the known standard volume typically is around 500 milliliters, corresponding to approximately 1 pint. Furthermore, it would have been obvious, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

Regarding claim 13, modified Novak discloses all of the claim limitations as set forth above. Novak further discloses passing blood through inlet (13) into filter bag (10), through the filter and into casing (15) and then out through outlet tube (19) (See also C2/L23-34).

Using the filter of Motomura et al., the step of passing the blood through the filter would further involve removing an amount of virus from the blood or plasma, since it has been disclosed that the Motomura et al. filter removes HIV and others (Motomura et al. C3/L45-57).

6. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Novak (USP 2,341,114) in view of Motomura et al. (USP 5,667,684) and further in view of Mayes et al. (US 2002/0147282).

Regarding claim 4, modified Novak discloses all of the claim limitations as set forth above. Novak does not explicitly disclose that the membrane is a composite filter with a prefilter and a laminated virus removal filter with a non-woven fabric on one side.

Motomura et al. further discloses that there is a non-woven fabric provided (C5/L60-67) but does not explicitly set forth that there is a composite membrane with a prefilter.

Mayes et al. discloses a grafted hydrophilic chains onto hydrophobic polymers (Abstract) using a thin film composite membrane configuration ([0056]) wherein the thin film acts as the membrane and the porous support acts as a prefilter (since the thin film is formed on top of a porous support, the membrane would be capable of having a prefilter and a membrane).

Novak, Motomura et al., and Mayes et al. are combinable because they are concerned with the same field of endeavor, namely that of filtration

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the membrane of Novak to include using the non-woven fabric and

prefilter aspects as taught by Mayes et al. for the purpose of improved purification of the final desired product.

7. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Novak (USP 2,341,114) in view of Motomura et al. (USP 5,667,684) and further in view of Verkaart (USP 4,466,888).

Regarding claim 10, modified Novak discloses all of the claim limitations as set forth above. Novak does not explicitly disclose the use of a sponge-like adsorber in the first compartment.

Verkaart discloses a blood collecting bag with inlet and outlet ports with a membrane and laminated filter (abstract). Verkaart further discloses in figure 1 that there is a sponge like adsorber (84) in the first compartment (C6/L7-19).

Novak, Motomura et al., and Verkaart. are combinable because they are concerned with the same field of endeavor, namely that of plasma and blood purification.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the blood bag of Novak to include a sponge like adsorber as taught by Verkaart for the purpose of breaking up blood foam (Verkaart C6/L1-10).

8. Claims 12 and 14-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Novak (USP 2,341,114) in view of Motomura et al. (USP 5,667,684) and further in view of Pall et al. (USP 5,100,564).

Regarding claim 12, modified Novak discloses all of the claim limitations as set forth above. Novak does not explicitly set forth that the virus removal bag is aseptically

and fluid-tightly connected to at least one functional bag with a different function creating a closed, multi-bag system.

Pall et al. discloses a system for collecting a processing donated blood with a collection bag and multiple satellite bags (abstract) in figure 1 wherein bag 11 is a collection bag and bags 15 and 13 are satellite bags. The bags are connected via flexible tubing and are sealed (C6/L1-25). Furthermore, the bags would be connected aseptically since it is well known in the art to handle biological fluids for medical use in an aseptic manner.

Novak, Motomura et al., and Pall et al. are combinable because they are concerned with the same field of endeavor, namely that of plasma and blood purification.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the blood bag of Novak to include using it as a further purification step for collected blood by replaced satellite bag 15 or 13 of Pall et al. with the virus purification bag for the purpose of improving the safety of the purified collected donated blood.

Regarding claims 14 and 15, modified Novak discloses all of the claim limitations as set forth above. Novak does not explicitly set forth the step of providing centrifugal force or a pressure to the virus containing solution in the first compartment.

Pall et al. discloses a system for collecting a processing donated blood with a collection bag and multiple satellite bags (abstract) in figure 1 wherein bag 11 is a collection bag and bags 15 and 13 are satellite bags. The bags are connected via

flexible tubing and are sealed (C6/L1-25). Furthermore, the bags would be connected aseptically since it is well known in the art to handle biological fluids for medical use in an aseptic manner. Pall et al. further discloses the step of centrifuging the collected plasma satellite bag blood product in satellite bag 15 (C2/L5-25). The step of centrifuging would also promote a pressure to the suspension.

Novak, Motomura et al., and Pall et al. are combinable because they are concerned with the same field of endeavor, namely that of plasma and blood purification.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the blood bag of Novak to include using it as a further purification step for collected blood by replaced satellite bag 15 of Pall et al. with the virus purification bag and then centrifuging the bag to provide a force or pressure for separation for the purpose of improving the safety of the purified collected donated blood and decreasing the required purification time.

Regarding claims 16 and 17, Novak discloses all of the claim limitations as set forth above.

Motomura et al. further discloses that the membrane is used to treat whole blood and plasma (C7/L38-45).

Regarding claims 17-19, Novak discloses all of the claim limitations as set forth above.

Pall et al. further discloses that the satellite bags contain plasma or leukocyte removed plasma (C3/L15-50 – plasma and leukocyte removed plasma). Since the

blood is collected and then treated immediately, the plasma has never been frozen (see process of C1/L30-C2/L30 – wherein only an anticoagulant treatment is used).

Regarding claim 20, Pall et al. further discloses that the plasma is transfused into a patient after it has been processed into the satellite bag and centrifuged (C2/L25-27).

Regarding claim 21, modified Novak discloses all of the claim limitations as set forth above. Modified Novak further discloses all of the claim limitations with regards to the virus removal system as set forth above.

Pall et al. discloses a system for collecting a processing donated blood with a collection bag and multiple satellite bags (abstract) in figure 1 wherein bag 11 is a collection bag and bags 15 and 13 are satellite bags. The bags are connected via flexible tubing and are sealed (C6/L1-25). Furthermore, the bags would be connected aseptically since it is well known in the art to handle biological fluids for medical use in an aseptic manner. Pall et al. further discloses the step of centrifuging the collected plasma satellite bag blood product in satellite bag 15 (C2/L5-25). The step of centrifuging would also promote a pressure to the suspension.

Pall et al. further discloses collecting whole blood from a donor into a blood collection means (C1/L30-35),

Separating the collected blood into plasma and red cells by centrifugation (C1/L35-40),

Then introducing the plasma into a virus removal bag of Novak (bag 15).

The satellite bag containing the purified plasma is then transfused into a patient (C2/L25-27).

Regarding claim 22, Pall et al. further discloses that the plasma is transfused into a patient after it has been processed into the satellite bag and centrifuged (C2/L25-27).

Regarding claim 23, Motomura et al. further discloses that human or animal blood is being processed (C1/L5-15 – HIV is well known to be in monkey and human blood and it is a well known problem of HIV presence in human blood as well as the reference of "body fluid").

Conclusion

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

The following references all pertain to blood filtration bags and blood filtration membrane systems:

- Watanabe, USP 4,035,304
- Goudaliez et al., US 2003/0004453
- Rothman et al. USP 6,682,656
- Kraus et al. US 2004/0217055
- Boggs et al. USP 6,099,734
- Hotta et al. US 2004/0116676

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to DAVID C. MELLON whose telephone number is (571)270-7074. The examiner can normally be reached on Monday through Thursday 7:00am-4:30pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Sample can be reached on (571) 272-1376. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Tony G Soohoo/
Primary Examiner, Art Unit 1797

/D. C. M./
Examiner, Art Unit 1797